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NOTICE OF ALLOWANCE AND FEE(S) DUE

23838 7590 07/23/2008 KENYON & KENYON LLP

1500 K STREET N.W. SUITE 700 WASHINGTON DC 20005 EXAMINER

KIM, JENNIFER M

ART UNIT PAPER NUMBER

1617 DATE MAILED: 07/23/2008

ſ	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	10/623,114	07/18/2003	Yerramilli V.S.N. Murthy	051091-2001	4452

TITLE OF INVENTION: COMPOSITIONS CONTAINING PRODRUGS OF FLORFENICOL AND METHODS OF USE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	10/23/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless corrects maintenance fee notifica	correspondence includir ed below or directed oth tions.	ng the Patent, advance on nerwise in Block 1, by (a	rders and notification of n a) specifying a new corres					
CURRENT CORRESPOND	ENCE ADDRESS (Note: Use BI	ock 1 for any change of address)	pape	Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, much aveits own certificate of mailing or transmission.				estic mailings of the other accompanying formal drawing, must
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KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700			I hei State addr trans	reby certify that the es Postal Service we essed to the Mail smitted to the USP	is Fee(/ith sul Stop FO (57	e of Mailing or Trans s) Transmittal is being ficient postage for fire ISSUE FEE address I) 273-2885, on the d	mission g depo st class above late inc	on sited with the United s mail in an envelope e, or being facsimile dicated below.
WASHINGTON	I, DC 20005							(Depositor's name)
								(Signature)
								(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CO	NFIRMATION NO.
10/623,114	07/18/2003	•	Yerramilli V.S.N. Murthy			051091-2001		4452
TITLE OF INVENTION	: COMPOSITIONS CO	NTAINING PRODRUGS	S OF FLORFENICOL ANI	METHODS OF U	JSE			
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nonprovisional	NO	\$1440	\$300	\$0	\$0			10/23/2008
EXAM	IINER	ART UNIT	CLASS-SUBCLASS					
KIM, JEN	NIFER M	1617	514-554000	•				
1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTOSBI 222) attached. The Address' indication (or "Fee Address" Indication form PTOSBI 47; Rev 03-02 or more recent) attached. Use of a Custome Number is required.			(I) the names of up to or agents OR, alternativ (2) the name of a single registered attorney or a	of a single firm (having as a member a riney or agent) and the names of up to thent attorneys or agents. If no name is				
PLEASE NOTE: Uni recordation as set fort (A) NAME OF ASSIG	less an assignee is ident h in 37 CFR 3.11. Comp GNEE	ified below, no assignee pletion of this form is NO	THE PATENT (print or typ data will appear on the p. T a substitute for filing an (B) RESIDENCE: (CITY	atent. If an assign assignment. and STATE OR C	OUNT	TRY)		
4a. The following fee(s) ☐ Issue Fee	are submitted:	41	b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit can The Director is hereby overpayment, to Depo	se first reapply ar	is atta	viously paid issue fee sched.	showr	1 above)
	s SMALL ENTITY state	is. See 37 CFR 1.27.	☐ b. Applicant is no long					
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than to Office.	he applicant; a regi	stered.	attorney or agent; or th	ne assi	gnee or other party in
Authorized Signature				Date				
Typed or printed nam	e			Registration No.				
This collection of inform an application. Confiden submitting the completes this form and/or suggests Box 1450, Alexandria, V Alexandria, Virginia 223	nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC k13-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain or r 1.14. This collection is est depending upon the indiv e Chief Information Office COMPLETED FORMS TO	etain a benefit by t imated to take 12 i idual case. Any co r, U.S. Patent and D'THIS ADDRESS	he pub minuter mmen Trader S. SEN	lic which is to file (and is to complete, includir is on the amount of ti- nark Office, U.S. Dep D TO: Commissioner	d by th ng gath me you artmen for Par	te USPTO to process) hering, preparing, and u require to complete at of Commerce, P.O. tents, P.O. Box 1450,

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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



UNITED STATES PATENT AND TRADEMARK OFFICE

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KENYON & KENYON LLP			KIM, JENNIFER M			
1500 K STREET N.W.			ART UNIT	PAPER NUMBER		
SUITE 700 WASHINGTON, DC 20005			1617 DATE MAILED: 07/23/200	8		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 662 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 662 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)		
10/623,114	MURTHY ET AL.		
Examiner	Art Unit		
Jennifer Kim	1617		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to May 22, 2008.
- The allowed claim(s) is/are 34-37, 45-48 and 50-60 (renumbered as1-4, 5-8 and 9-19 respectively).
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) \square All b) ☐ Some* c) ☐ None of the:
 - 1. T Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No.
 - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08).
- Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7.

 Examiner's Amendment/Comment
- 8. T Examiner's Statement of Reasons for Allowance
- Other .

/Jennifer Kim/ Primary Examiner, Art Unit 1617

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The previously withdrawn method claims have been rejoined.

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious the claimed composition comprising specific salt of florfenicol i.e. florfenicol butyrate and a pharmaceutically acceptable solvent set forth in claim 34.

Applicants' declaration showing unexpected result of only florfenicol butyrate showing superior pharmacokinetic profile compared with other salts of florfenicol such as acetate and hexanoate is persuasive.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/ Primary Examiner, Art Unit 1617

Jmk July 7, 2008